EMM
Exact Medical Manufacturing, Inc.

AUG 2 6 2011

K111535

Sec. 6: 510(k) Summary – Surgical Gown-Spunlace w/PE Layer, rev. 072511

510(k) Summary for Exact Medical Manufacturing Inc., Surgical Gowns – Spunlace w/PE Layer

Date Summary was Prepared	June 1, 2011
510(k) Submitter	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street Lancaster, NY 14043 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110
Primary Contact for this 510(k) Submission	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street Lancaster, NY 14043 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110
Device Common Name	Surgical Gown
Trade Name	Surgical Gown – Spunlace w/PE Layer
Device Product Codes and Classification Name	FYA, 21CFR878.4040, Surgical Apparel, Class II
Predicate Device	Medline (Proxima) Surgical Gowns 510(k)964142
Device Description	Exact Medical Manufacturing Surgical Gown-SPL are single use, disposable surgical gowns using in the OR as a protective covering, for the operating room staff, from the transfer of microorganisms, body fluids and particulates. Exact Medical Manufacturing Surgical Gowns-Spunlace w/PE Layer are comprised of disposable nonwoven (Spunlace), 100% polyester cuffs, Velcro neck closure, reinforced areas fabric or polyethylene
Intended Use	Device Name: Exact Medical Manufacturing Surgical Gowns-Spunlace w/PE Layer Model Numbers 18-201L, 18-201-XL, 18-201 XXL and 18-201 XLXL Indications for Use: Exact Medical Manufacturing Surgical Gown – Spunlace w/PE Layer are sterile or non-sterile single use devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The Exact Medical Manufacturing Surgical Gown – Spunlace w/PE Layer are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization. Sterilization method: ETO (ethylene oxide) Standard: AAMI 11135-1:2007, Sterilization of Healthcare Products Pre-Conditioning: Temperature C° = 42 RH% = 60 Dwell Time Hours = 6 EO Cycle: Temperature C° = 54 RH% =/> 30 EO Concentration = 730mg/m^3 Dwell Time Hours = 9 Aeration: Temperature = ambient Time =/> 72 hours EO Residuals; EO=4mg max., ECH=9mg. max.
Technological Characteristics	Exact Medical Manufacturing Surgical Gowns-Spunlace w/PE Layer have the same design, material and performance characteristics of the predicate device.
Summary of Testing	Exact Medical Manufacturing Surgical Gowns-Spunlace w/PE Layer is substantially equivalent and meets the same acceptance criteria as the predicate device/gown in K964142. Non-clinical performance testing includes: Biocompatibility (cytotoxicity, irritation, sensitization) in compliance with the methods of ISO 10993, Barrier properties, tensile, tear strength, flammability, linting and sterility. All results of the testing met acceptance criteria.
Substantial Equivalence Conclusion	The surgical gowns described in this 510(k) submission are substantially equivalent in all specifications and performance compared to the predicate device indentified in K964142 and do not present any differences that could raise concerns related safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exact Medical Manufacturing, Inc.
% Mr. Robert O. Dean
President
Compliance Systems International, LLC.
1083 Delaware Avenue
Buffalo, NY 14209

AUG 26 2011

Re: K111535
Trade/Device Name: EMM Surgical Gowns-Spunlace w/PE Layer
Models: 18-201 L, 18-201 XL, 18-201 XXL, and 18-201 XLXL
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: July 28, 2011
Received: August 1, 2011

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

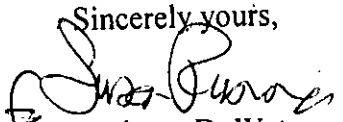
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111535

Indications for Use Form

Indications for Use:

510(k) Number (if known): K111535

Device Name: Exact Medical Manufacturing Surgical Gowns-Spunlace w/PE Layer Model Numbers 18-201L, 18-201-XL, 18-201 XXL and 18-201 XLXL Indications for Use: Exact Medical Manufacturing Surgical Gown – Spunlace w/PE Layer are sterile or non-sterile single use devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

The Exact Medical Manufacturing Surgical Gown – Spunlace w/PE Layer are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization.

Sterilization method: ETO (ethylene oxide)

Standard: AAMI 11135-1:2007, Sterilization of Healthcare Products

Pre-Conditioning: Temperature C^{o} = 42

RH% = 60

Dwell Time Hours = 6

EO Cycle: Temperature C^{o} = 54

RH% =/> 30

EO Concentration = 730mg/m^3

Dwell Time Hours = 9

Aeration: Temperature = ambient

Time =/> 72 hours

EO Residuals; EO=4mg max., ECH=9mg. max.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111535